DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 1, 2015

Coeur, Inc.
Ms. Erin Rheinscheld
Regulatory Analyst
100 Physicians Way
Suite 200
Lebanon, Tennessee 37090

Re: K142745
Trade/Device Name: 125ml CT Syringe
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: February 12, 2015
Received: February 18, 2015

Dear Ms. Rheinscheld,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142745

Device Name: 125mL CT Syringe

Indications For Use:

For use with the Liebel-Flarsheim Optivantage and Liebel-Flarsheim CT 9000 ADV Injectors for the injection of contrast media or saline.

Prescription Use _√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Coeur, Inc.

125mL CT Syringe

510(k) Summary

1. Submitter:

Name:	Coeur, Inc.
Address:	100 Physicians Way, Suite 200 Lebanon, TN 37090 Owner/Operator Number: 9038672
Phone:	(615) 547-7923 (Corporate Office)
Fax:	(615) 547-7937 (Corporate Fax)
Contact:	Erin Rheinscheld, Regulatory Analyst
Date:	March 23, 2015

2. Device:

Trade/Proprietary Name:	125mL CT Syringe
Common/Usual Name:	125mL CT Syringe
Classification Name:	Accessory, Injector and Syringe, Angiographic

3. Legally Marketed Device to which Substantial Equivalence is claimed:

Coeur 130mL Syringe, K971712

4. Device Description: The 125mL CT Syringe will be sold as a single syringe. The following configurations may also be offered:

i. **125mL Syringe and Fill Tube**
ii. **125mL Syringe with Coiled Line and Spike**
iii. **2 – 125mL Syringes with 2 Spikes**
iv. **125mL Syringe and Coiled Extension Line**
v. **2 – 125mL Syringes with Extension Y-Line and 2 Spikes**

5. Intended Use of Device: For use with the Liebel-Flarsheim Optivantage and Liebel-Flarsheim CT 9000 ADV Injectors for the injection of contrast media or saline.

6. Summary of Technological Characteristics As Compared to Predicate Devices: The intended use (injection of contrast media or saline), the method of use (pressure), and the fluid path materials of the proposed device are the same as the legally-marketed device. The components (accessories) are also the same as legally-marketed devices.

If Substantial Equivalence was based on an Assessment of Performance Data, the following information is also provided:

1. **Nonclinical Tests Submitted:** Testing used to verify substantial equivalence including an assessment of Performance Data for the proposed device, including:

a. **Visual Verification of the Products -** Inspection of the product for conformance to visual requirements.
b. **Dimensional Evaluation of the Products** – Inspection of the product to verify dimensional acceptance.
    i. ISO 594-2:1998 – Syringe evaluation to dimensional requirements of the ISO 594-2 standard using go/no go gage.
    ii. Injector Fit :
        1. Evaluation of product for fit and function with the Optivantage DH Injector.
        2. Evaluation of product for fit and function with the CT 9000ADV Injector.
    iii. Volume – Evaluation for volume accuracy when used with injectors.
c. **Functional Verification of the Products**:
    i. Dynamic testing where the syringe is tested at a minimum of 330psi in simulated injections.
    ii. Failure testing follow dynamic testing, where syringes are pressurized under increasing pressures until failure is observed.
d. **Other**
    i. ISO 594-2:1998 – Syringe evaluation to requirements of the ISO 594-2 standard
    ii. ISO 7886-2:1996 – Syringe evaluation to applicable requirements of the ISO 7886 standard.
e. **Age Verification** – Based on the packaging and testing of accelerated aged samples, the initial expiration of the device is 2 years. The methods and testing used to support new shelf life claims will be the same as those defined to support the 2-year shelf life identified in the submission
f. **Biocompatibility** – While the proposed device is made of the same materials in contact with the fluid path as that cleared under K971712, biocompatibility testing was conducted on the device. Other accessories are identical to previously marketed accessories or biocompatibility testing was also conducted.

2. Clinical Tests Submitted: NA

3. Conclusions Drawn from Nonclinical and Clinical Tests Submitted: The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to the predicate devices identified.